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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,910	10/16/2003	Alec Ginggen	MED0010	7472
27777	7590	06/15/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,910

Applicant(s)

GINGGEN ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4, 5, 8, 9-12, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0055009 to Rosenberg et al.

In the specification and figures, Rosenberg discloses the device claimed by applicant. With particular regard to claims 1, 4, 5, 8, 9, and 14, Rosenberg discloses an adjustable resistance valve 40 with an actuator 42 allowing the selection of the resistance to flow of the valve, a selection mechanism disc 46, and a multi-lumen resistance catheter with a set of parallel longitudinal resistors 48a or varying diameter, wherein the range of resistance may be 0-50 mm Hg/mL/min (see paragraphs 0031, 0032, 0035).

With regard to claim 10, the actuator may comprises a motor, an energy source (controller 60) and connectors, and sensors that provide feedback as to the resistance of the system (see paragraphs 0027, 0029, 0032, 0034).

With regard to claims 11 and 12, the shunt system comprises a proximal ventricular catheter 32 and a distal drainage catheter 34 (see paragraph 0025)

connected and implanted as claimed by applicant. The valve is positioned within the catheter system 30 such as to allow CSF to traverse the aperture within the valve (see paragraph 0032).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over 2005/0055009 to Rosenberg in view of US 3,170,483 to Milroy.

Rosenberg discloses the device substantially as claimed (see rejection above) with the exception of varying the lengths of the passages in the resistance system to vary the resistance to flow. Kinsler specifically teaches a set of passages 29 in a disk 33 that vary in cross-sectional area in order to provide greater or lesser resistance to flow in the valve. A user may select the desired resistance by rotating the disk 33 to align the desired jet 29 with the outlet passage 27 (see column 3, lines 1-17).

Milroy discloses a flow regulator valve with an inlet 70, outlet 72, and a flow-regulator or throttling means 74. The throttling means comprises a series of tubes 62 that traverse the longitudinal axis of the valve housing 80. Variations in both the length and diameter of the tubes 62 provide varying resistance to flow through the tubes (see column 5, lines 40-65, FIG 6). Therefore, it would have been obvious to alter fluid

resistance through the passages of the Rubenstein resistance system by varying either the diameter or the length of the passages as disclosed by Milroy, since both variations were art-recognized equivalents at the time the invention was made, and one of ordinary skill in the art would have found it obvious to substitute a variation in length of the passage for a variation in the cross section of the passage. See MPEP 2144.06.

5. Claims 1, 4, 5, and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,615,691 to Hakim in view of US 4,148,460 to Kinsler.

Hakim discloses, in the specification and the figures, the device substantially as claimed by applicant. With particular regard to claims 1, 4, 5, 8, 9, and 11-13, Hakim discloses a cerebrospinal fluid shunt or catheter 18 with an inlet end (at side 18) and an outlet end (at side 20, see FIG 1). The shunt comprises two valves, 12 and 14 (see claim 13). Adjustable valve 14 comprises actuator or rotor 72 that adjusts the resistance to flow across ball valve 32 through valve seat 30 (see column 3, lines 43-67, column 4, lines 1-27). Hakim teaches that adjustable CSF valves are desirable to allow precise control of flow through the shunt depending on patient parameters. Hakim further discloses a range of valve opening pressures (see column 5, lines 31-33).

Hakim fails to disclose a resistance system with a circular set of passages of varying resistance to flow. Kinsler discloses a multi-port fluid flow control valve with fluid inlet 25, outlet 27, and chamber 11 (see column 2, lines 8-23, FIGS 1-2). The valve further comprises a flow control device comprising a circular disk 33 with a series of openings or jets 29 that traverse the longitudinal axis of the disk and vary in cross-sectional area (see claims 4-5, 8-9), providing varying resistance to flow through the

outlet 27 (see column 2, lines 35-50). A user may select the desired resistance by rotating the disk 33 to align the desired jet 29 with the outlet passage 27 (see column 3, lines 1-17). The adjustable valve disclosed by Kinsler provides flexibility in choices of flow rates and sequences, as well as minimizing wear and tear on the valve parts (see column 1, lines 30-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the adjustable valve disclosed by Kinsler for the valve disclosed by Hakim in order to provide choices of flow rates while minimizing wear and tear on the valve, as taught by Kinsler.

With regard to claim 1, applicant claims a “means for selecting” a passage across the valve. Applicant appears to be invoking 35 USC 112, 6th paragraph means-plus-function interpretation of the limitation by presenting the limitation in “means for” language along with functional language, absent any structural recitations. (See MPEP 2181 for guidelines regarding the use and interpretation of “means for” language.) A claim limitation expressed in means-plus-function language shall be construed to cover the corresponding structure described in the specification and equivalents thereof. Claims 8-9, in reciting structural limitations drawn to the “means for selecting” are interpreted only by the metes and bounds of the claim specification itself, without turning to the specification for interpretation.

Turning to applicant’s specification, page 5, applicant describes the “means for selecting” to comprise disk 2 with passages traversing the disk. Therefore, Examiner has interpreted the “means for selecting” claimed by applicant to correspond to disc 2 in FIG 1a. Kinsler’s circular disk 33 performs the same function as applicant’s “means for

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selecting,” is not excluded in any specific definition of the “means for selecting,” and is equivalent to applicant’s circular “means for selecting,” disk 2 (see MPEP 2183).

Therefore, applicant’s invention is unpatentable over the prior art.

With regard to claim 10, Hakim discloses that the adjustable valve 14 comprises a stepping motor that allows rotation of a rotor 72 based on the signals generated by electromagnets 92, 93, 94, and 95, and received by stator elements 78. The stator elements move rotor 72 to adjust the resistance to fluid flow through the valve. Hakim further discloses a control device 96 that controls the movement of the rotor 72 and comprises input keys and a display (see FIG 12). The controller 96 is capable of providing feedback to the user and managing the energy consumption of the device, since it sends commands to the electromagnets.

With regard to applicant’s limitations drawn to the operation of the motor of claim 10, such limitations are held to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the motor disclosed by Hakim is capable of performing as claimed by applicant, meeting the limitations of the claims.

With regard to applicant’s claim limitations drawn to the size of the passages selected to cover a range of resistances, such a modification is within the skill of a worker in the art. Hakim teaches specifically that the adjustable valve of his device may be rotated to select an operating pressure within a disclosed range (see column 5, lines

31-33). Variable resistance valves regulate the flow of fluid therethrough by varying the resistance, or opening pressure of the valve. Hakim specifically discloses that the flow of CSF may be controlled by adjusting the opening pressure of the valve, necessarily altering the valve's resistance to flow. It has been held that where the general conditions of a claim (such as adjusting the opening pressure of an adjustable valve within a disclosed range to control flow resistance) are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05.

6. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,615,691 to Hakim in view of US 4,148,460 to Kinsler, further in view of US 3,170,483 to Milroy.

Hakim and Kinsler disclose the device substantially as claimed by applicant (see rejection above) with the exception of varying the lengths of the passages in the resistance system to vary the resistance to flow. Kinsler specifically teaches a set of passages 29 in a disk 33 that vary in cross-sectional area in order to provide greater or lesser resistance to flow in the valve. A user may select the desired resistance by rotating the disk 33 to align the desired jet 29 with the outlet passage 27 (see column 3, lines 1-17).

Milroy discloses a flow regulator valve with an inlet 70, outlet 72, and a flow-regulator or throttling means 74. The throttling means comprises a series of tubes 62 that traverse the longitudinal axis of the valve housing 80. Variations in both the length and diameter of the tubes 62 provide varying resistance to flow through the tubes (see column 5, lines 40-65, FIG 6). Therefore, it would have been obvious to alter fluid

resistance through the passages of the Hakim/Kinsler resistance system by varying either the diameter or the length of the passages as disclosed by Milroy, since both variations were art-recognized equivalents at the time the invention was made, and one of ordinary skill in the art would have found it obvious to substitute a variation in length of the passage for a variation in the cross section of the passage. See MPEP 2144.06.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,615,691 to Hakim in view of US 4,148,460 to Kinsler, as applied above, further in view of US 6,264,625 to Rubenstein et al.

Claim 14 recites a method for treating hydrocephalus comprising the steps of implanting and properly placing a catheter, along with a preamble that recites structural limitations of the device. Hakim discloses the shunt as claimed with proximal and distal catheters and an adjustable valve. Hakim, as modified by Kinsler, discloses the resistance system with multiple passages with varied resistance to flow and the rotational movement of the resistance system to control fluid flow.

Neither reference specifically discloses that the catheter ends are implanted proximally in the brain ventricles and distally in a reabsorption site. However, Hakim discloses specifically that his shunt comprises a cerebroventricular catheter that is surgically implanted following well-known procedures. Rubenstein discloses an apparatus and method for treating a patient comprising the insertion and placement of a cerebrospinal fluid shunt that shunts fluid from a proximal end in a patient's ventricle, through a regulating valve, to the patient's peritoneum (see column 18, lines 16-28, FIG 10a). The method allows excess fluid to drain from the patient's intracranial space to a

site where it may be reabsorbed by the body (see Rubenstein, column 2, lines 54-65). Therefore, it would have been obvious to insert and guide the catheter with variable control valve disclosed by Hakim and Kinsler to the locations disclosed by Rubenstein since Hakim teaches that the shunt may be implanted by procedures known in the art, and Rubenstein teaches such a procedure to redirect excess fluid in the patient.

Response to Arguments

8. Applicant's amendment filed 17 April 2006 has been entered and considered.

9. Applicant's arguments filed 17 April 2006 have been fully considered but they are not persuasive.

10. Applicant argues that the Milroy device functions in a manner different than the claimed device. Specifically, Milroy allows fluid to flow through multiple passages of varying length, defining differing resistances to flow, at the same time, in order to achieve a desired fluid resistance. Applicant argues that the present invention guides fluid flow to a single selected passage to achieve a desired resistance to flow. To the contrary, applicant's claims recite specifically that the fluid flowing through the valve may traverse "at least one passage" of the selecting means (see claim 1, line 7, claim 11, line 13, claim 14, line 11). The instant invention allows passage of fluid through more than one passage at a time, and the Milroy disclosure, in combination with the teachings of the other prior art of record, meets the limitations of the claims.

11. Applicant further argues that the prior art fails to disclose or suggest any range of resistance to flow through the adjustable valves. To the contrary, Hakim specifically

discloses a range of opening pressures of the disclosed valve, which necessarily affects the valve's resistance to flow. Since the prior art does, in fact, give a range that may be correlated with desired resistance, one of ordinary skill in the art at the time the invention was made would have the skill to adjust the opening pressures of the adjustable valve to achieve the resistance to flow claimed by applicant.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,095,491 Kriesel
 - i. In-line flow rate control device with rotary flow resistance control

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

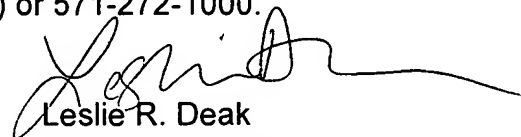
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER



Leslie R. Deak
Patent Examiner
Art Unit 3761
1 June 2006